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July 13, 2016

To: Audit Committee

From: Sachi A. Hamai
Chief Executive Officer

APPROVAL OF PROPOSED BOARD POLICY FOR PROCEDURES TO ENSURE THE LEGAL PROTECTIONS OF PATIENT SAFETY WORK PRODUCT AND REPORTING TO A THIRD PARTY PATIENT SAFETY ORGANIZATION

The Chief Executive Office (CEO) seeks the Board's approval for the proposed Board Policy for procedures to ensure the legal protections of Patient Safety Work Product and reporting to a third party Patient Safety Organization (PSO).

The Patient Safety and Quality Improvement Act of 2005 (PSQIA) established the Patient Safety Evaluation System as the method by which healthcare providers develop and analyze patient safety information for reporting to a PSO. The PSQIA defines the information that is collected, developed, and analyzed for the purpose of improving patient safety, healthcare quality, and healthcare outcomes, and reports to a PSO as Patient Safety Work Product.

This proposed Board Policy creates a formal PSO policy which affords the County legal protections when analyzing confidential information that could help with the quality and improvement of patient safety.

The proposed Board Policy was approved by the County Legal Exposure Reduction Committee's Medical Malpractice Sub-Committee on May 19, 2016; and approved by the Health and Mental Health Cluster on June 22, 2016.

If you have any questions, please contact Destiny Castro at (213) 738-2194 or dcastro@ceo.lacounty.gov.

SAH:JJ
STR:DC:sg

Attachment

c: Executive Officer, Board of Supervisors
County Counsel
Director of Personnel

i:\RMB Secs\Board letters, memos, policies\Board Policies\M to Audit Committee re Proposed Board Policy - Patient Safety Organization (PSO) 7-13-16.docx

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Los Angeles County BOARD OF SUPERVISORS POLICY MANUAL

Policy #:	Title:	Effective Date:
Proposed	Procedures to Ensure the Legal Protections of Patient Safety Work Product and Reporting to a Third Party Patient Safety Organization	

PURPOSE

To establish a Patient Safety Evaluation System (PSES) to effectively manage the flow of patient safety work product (PSWP) to ensure the legal protections provided by the Patient Safety and Quality Improvement Act of 2005 (PSQIA).

REFERENCE

Federal Register, Vol. 73, No. 226, Patient Safety and Quality Improvement, Final Rule, pp 70732-7081 4, November 21, 2008

42 Code of Federal Regulations (CFR) Part 3

POLICY

This policy shall apply to all Los Angeles County providers of health care, including but not limited to, providers working for the County of Los Angeles (County) Department of Health Services, Department of Mental Health, Department of Public Health, Fire Department, and the Sheriff's Department.

The County has a designated Patient Safety Organization (PSO). The PSO is considered a business associate of the County and its patient safety activities are deemed health care operations covered under the Health Insurance Portability and Accountability Act (HIPAA) Privacy rule.

Los Angeles County health care facilities and programs shall enter event information into the Safety Intelligence (SI) system pursuant to their respective departmental policies. The SI is an essential component of the County's PSES and provides the platform to manage the flow of patient safety work product (PSWP). Event information and supporting materials developed within the PSES and defined by each County health care facility or program shall be deemed PSWP. Facilities will collect data, conduct analysis, and report information to the PSO for the primary purpose of improving patient safety. The PSO will collect and analyze the PSWP for the purpose of improving patient safety, health care quality, and health care outcomes. County health care facilities and programs will review

the information analysis generated by the PSO for the purpose of improving patient safety, health care quality, and health care outcomes. The PSWP, the activities of the PSES, and the information analysis provided by the PSO is considered privileged and protected when used for patient safety improvement efforts and shall not be disclosed unless an exception applies. Any person who knowingly or recklessly discloses identifiable PSWP in violation of the confidentiality protection is subject to the monetary penalty of not more than \$10,000 for each act constituting a violation as prescribed in the PSQIA.

The County PSES consists of, but is not limited to, activities (including data collection, analysis processes, databases, and meetings [regardless of method]) as described below:

- Quality assessment, quality improvement, and quality assurance activities;
- Safety Intelligence (SI) system;
- Peer review;
- Other patient safety activities; and
- Corrective Action Plans (CAPs).

Each County health care facility or program may consider the following elements for inclusion in departmental policies that define their respective patient safety activities:

- the scope of the PSES;
- the process for identifying and documenting PSWP in the PSES; and
- the description of the flow of PSWP for reporting to the PSO.

DEFINITIONS:

Confidential means not subject to disclosure. Exceptions to confidentiality are: 1) disclosure of PSWP to carry out PSA; 2) disclosure of non-identifiable PSWP; 3) disclosure of PSWP to grantees, contractors, and certain entities carrying out research or evaluation of demonstration projects as defined in Section 922 of PSQIA; 4) disclosure to the Food and Drug Administration with respect to a product or activity related to that agency; 5) voluntary disclosure of PSWP by a provider to an accrediting body that accredits the provider; 6) disclosure of PSWP to law enforcement authorities relating to the commission of a crime (or to an event reasonably believed to be a crime) if person making the disclosure of PSWP reasonably believes that such disclosure is necessary for criminal law enforcement purposes; 7) other disclosures established by Federal regulation that are necessary for business operations and are consistent with PSQIA; or 8) with respect to persons other than a PSO, the disclosure of PSWP that does not include materials that assess the quality of care of an identifiable provider or describe or pertain to one or more actions or failures to act by an identifiable provider. PSWP disclosed as an exception shall continue to be confidential.

Patient Safety Organization (PSO) means a private or public entity or component thereof that is listed by the Secretary pursuant to section 924(d) of the Public Service Act, 42 U.S.C. 299b-24. The PSO will collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery.

Patient Safety Evaluation System (PSES) means the collection, management, or analysis of information for reporting to or by a PSO. The PSES serves as the interface for data collection and analysis between the County health care facilities and programs, and the PSO.

Patient Safety Work Product (PSWP) means any data reports, records, memoranda, analyses (such as Root Cause Analyses), or written or oral statements (or copies of any of this material) that: 1) are assembled or developed by a County health care facility or program for reporting to the PSO and are reported to the PSO, which includes information that is documented as within a PSES for reporting to a PSO; 2) are developed by the PSO for the conduct of patient safety and which could result in improved patient safety, health care quality or health outcomes; or 3) identify or constitute the deliberations or analysis of, or identify the fact of reporting pursuant to, a PSES (such as the date the information entered the PSES). County health care facilities and programs may submit the information pursuant to the County-PSO Functional Reporting Agreement. Information created, or analysis generated, by a County health care facility or program within a PSES for reporting to a PSO is considered PSWP even if not reported to the PSO, so long as the PSO is authorized to access such information. Information removed from the PSES is no longer considered eligible for protection. PSWP does not include a patient's medical record, billing and discharge information, or any other original patient or provider information; nor does it include information that is collected, maintained, or developed separately, or exists separately, from the PSES. PSWP will be date-stamped when collected, when deliberated, when removed, and when reported to the PSO.

Patient Safety Activities means: 1) efforts to improve patient safety and quality of health care delivery; 2) the collection and analysis of PSWP; 3) the development and dissemination of information with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices; 4) the utilization of the PSWP for purposes of encouraging a culture of safety and of providing feedback and assistance to minimize patient risk; 5) the maintenance of procedures to preserve confidentiality with respect to PSWP; 6) the provision of appropriate security measures with respect to PSWP; 7) the utilization of qualified staff; and 8) activities related to the operation of a PSES and to the provision of feedback to participants in a PSES.

Privileged means PSWP that is: 1) not subject to Federal, State, or local civil, criminal, or administrative subpoena or order, including in a Federal, State, or local civil administrative disciplinary proceeding against a provider; 2) not subject to discovery in connection with a Federal, State, or local civil, criminal, or administrative proceeding, including in a Federal, State, or local civil or administrative disciplinary proceeding against a provider; 3) not subject to disclosure under the Freedom of Information Act; the California Public Records Act, or any other similar Federal, State, or local law; 4) not admitted as evidence in a Federal, State, or local civil proceeding, criminal proceeding, administrative rulemaking proceeding, or administrative adjudication proceeding, including any such proceeding against a provider; or 5) not admitted in a professional disciplinary proceeding of a professional disciplinary body established or specifically authorized under State law. Exception to privilege is voluntary disclosure of non-identifiable PSWP. PSWP disclosed as an exception shall continue to be privileged.

RESPONSIBLE DEPARTMENT

Sheriff's Department

Chief Executive Office

Fire Department

Department of Health Services

Department of Mental Health

Department of Public Health

DATE ISSUED/SUNSET DATE

Issue Date:

Sunset Review Date: